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09/855,542	05/16/2001	Rajesh Manchanda	BERLX-100	9728

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EXAMINER

SHARAREH, SHAHNAM J

ART UNIT PAPER NUMBER

1617

DATE MAILED: 03/14/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

**Application No.**

09/855,542

**Applicant(s)**

MANCHANDA, RAJESH

**Examiner**

Shahnam Sharareh

**Art Unit**

1617

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 08 December 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-4, 6-22 and 32-34 is/are pending in the application.
- 4a) Of the above claim(s) 7, 11-14, 16-22 and 34 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-4, 6, 8-10, 32-33 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: \_\_\_\_\_

### **DETAILED ACTION**

Applicant's submission filed on December 08, 2005 has been entered.

Examination of the claims to the extent that they read on the elected species: Tc-99m, depreotide and iodide ion, as filed in the reply of June 13, 2005 continues Claims 1-4, 6-10, 32-33 are pending. Applicant argues again that since the claims have been fully searched no serious burden is imposed on the Examiner. In reply, Examiner restates previous position that the full scope of the presented claims were never examined throughout the prosecution and Applicants' claim amendments have modified the scope of the originally presented claims. Accordingly, the restriction requirement was properly made. At no point during the examination of this application, had examiner made any statement that the search was extended beyond the scope of the elected species. Nor is there any evidence on record that the examination was extended to the entire scope of the claims and beyond the originally elected species.

Moreover, Examiner has pointed out that the Restriction Requirement is discretionary to expedite the prosecution. Since the scopes of the claims have been modified throughout the prosecution, Examiner has requested for a Restriction Requirement based on the guidelines articulated in MPEP § 806. Accordingly, as classification is prima facie evidence of undue burden of search, the examiner has established reasons for the Restriction Requirement.

Applicant argues that different classification by itself do not amount to an undue burden of search. However, Applicant's has failed to point out the legal authority of

such conclusion. For such reasons of record, the requirement filed on May 23, 2005, the requirement is still deemed proper.

Claims 7, 11-14, 16-22, 34 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention and species, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on June 13, 2005.

Claims 1-4, 6, 8-10, 32-33 are under consideration.

Any rejection that is not addressed in this Office Action is considered obviated in view of the amendments.

***Claim Rejections - 35 USC § 103***

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1-4, 6, 8-10, 32-33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Solanki US Patent 5,262,175 in view of Cyr et al US Patent US 6,881,396.

The instant claims are directed to compositions comprising a radionuclide such as Tc-99m, a targeting agent preferably a peptide, and iodide ions.

Solanki teaches the use of weak oxidizing agents such as iodine, iodophores and povidone iodine to stabilize the radiopharmaceutical complex compositions. (col 2, lines 1-8). Solanki teaches preparing a Tc-99 containing composition by mixing lyophilized Tc-99m hexamethylpropyleneaminoxime (HMPAO) complex with 0.4 mg of sodium iodide or potassium iodide. (see col 7, line 55- col 8, line 50). Solanki then claims

Art Unit: 1617

methods of stabilizing a radiopharmaceutical complex with weak oxidizing agents such as iodine, iodophores and povidone-iodine. (see col 8, line 50-col 9, line 5). Solanki teaches the addition of weak oxidizing agents such as iodine salts to radiopharmaceutical complexes including Tc-labeled compositions. The sodium iodide or potassium iodide and further the iodine component of Solanki is viewed to meet the instant limitation "iodide ion or iodide ion generating compound," because even iodine component can read on the term "compound which generates iodide ions." Solanki only fails to specifically recite the use of depreotide in his formulations.

Cyr is used to establish the state of art in using targeting peptides as stabilizers to increase the shelf life of radiopharmaceuticals (see col 5-15). Cry specifically teaches the use of Tc-labelled somatostatin receptor-binding peptide deproetide (col 15, line 1-col 18; col 44, lines 36-59). Cyr also encourages the addition of any suitable pharmaceutical agent for preparing his formulations (col 15, lines 8-40). Applicant is also put in notice that Cyr's effective filing date antedates the effective filing date of the instant application, because Cyr's CIP parent application adequately described the instantly relied teachings. (see attached priority documents at pages 22-27 of US App 09/695,360, now abandoned). Thus, Cyr is a competent prior art.

It has been held *prima facie* obvious to combine two compositions each of which is taught by prior art to be useful for same purpose in order to form third composition that is to be used for very same purpose; idea of combining them flows logically from their having been individually taught in prior art. *In re Kerkhoven*, 205 USPQ 1069 (CCPA 1980). Accordingly, it would have been obvious to one of ordinary skill in the art

at the time of invention to combine a weak oxidizing agent such as iodine salts of Solanki with the Tc-labelled formulations of Cyr, because both formulations are directed for the same purpose and combining them would flow logically from their having been individually taught in prior art.

Further, as stated by Solanki, the ordinary skill in the art would have had a reasonable expectation of success in achieving a stable radiopharmaceutical formulation when adding iodine salt described by Solanki, to a Tc-labelled containing radiopharmaceutical compositions.

### ***Response to Arguments***

Applicant's arguments filed December 8, 2005 have been fully considered but they are not persuasive.

First applicant argues that the Iodine in Solanki is not equivalent to a disclosure of the use of iodine ions. (see page 13, 3<sup>rd</sup> para. of the remarks). In response, Examiner states that such lines of arguments are not persuasive, because not only Solanki discloses the use of sodium or potassium iodides, but also the use of iodine itself. Clearly, the language of iodine in Solanki at least read on compounds that generate iodide ions. Furthermore, Solanki's invention relies on the use of halogen releasing agents including iodide ions (col 2, lines 1-11). Specifically, Solanki teaches the use of other oxidizing agents including iodine or its derivatives. Thus, Solanki clearly provides for the use of halogen releasing agents such as iodide ions in his compositions.

In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by

Art Unit: 1617

combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, the knowledge generally available to one of ordinary skill in the art.

Applicant argues that there is no reason for example to conclude that the use of a stabilizer is necessary or desired for stabilizing radiopharmaceutical agents of Cry and the ordinary skill in the art would have to pick and choose different components from the cited references. (see arguments at page 15 of the remarks).

In response, Examiner states that since it is generally known in the art to use a weak oxidizing agent to improve stability of radiopharmaceutical agents, such knowledge would have been available to the one of ordinary skill in the art to employ. Furthermore, "Obviousness does not require absolute predictability of success." Indeed, for many inventions that seem quite obvious, there is no absolute predictability of success until the invention is reduced to practice. *In re Merck & Co*, 800 F.2d at 1098, 231 USPQ at 380. For obviousness under §103, all that is required is a reasonable expectation of success. *In re Longi*, 759 F.2d 887, 897, 225 USPQ 645, 651-52 (Fed. Cir. 1985). Here, since both cited art are in the same field of endeavor, one of ordinary skill in the art would have had a reasonable expectation of success in employing the teachings provided by both references. The primary reference only suggests a number of halogen releasing agents for use as stabilizers. Thus, therefore

Art Unit: 1617

selecting such agents to reach the claimed intended purpose would not have been considered an impermissible picking or choosing. For such reasons, the claims stand rejected.

### ***Conclusion***

No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shahnam Sharareh whose telephone number is 571-272-0630. The examiner can normally be reached on 8:30 am - 6:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan, PhD can be reached on 571-272-0629. The



Art Unit: 1617

fax phone number for the organization where this application or proceeding is assigned  
is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

**SS**

Radmanella